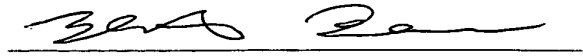
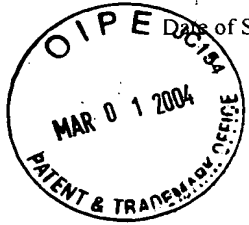


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Date of Signature and Deposit: February 27, 2004

  
Zhibin Ren 47,897



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Patrick H. Roseboom, et al.

Date: February 27, 2004

Serial No.: 10/676,526

Group Art Unit: --

Filed: 10/01/2003

Examiner: --

Title: PROMOTER SEQUENCES FOR  
CORTICOTROPIN RELEASING-FACTOR  
BINDING PROTEIN AND USE THEREOF

File: 960296.98687

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INFORMATION DISCLOSURE STATEMENT

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Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

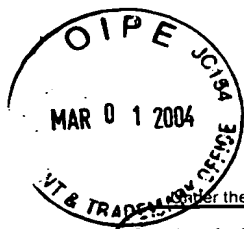
Enclosed is a completed Information Disclosure Statement by Applicant listing documents that the applicant in the above-identified application wishes to bring to the attention of the Examiner for consideration in connection with the examination on the merits of this application.

No fee is believed due in connection with this submission. However, if a fee is due, please charge the fee to Deposit Account No. 17-0055.

Respectfully submitted,



Zhibin Ren  
Reg. No. 47,897  
Attorney for Applicants  
QUARLES & BRADY LLP  
411 East Wisconsin Ave.  
Milwaukee, WI 53202  
TEL 414-277-5633  
FAX 414-277-3552



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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

1

of

4

### Complete if Known

Application Number

10/676,526

Filing Date

10/01/2003

First Named Inventor

Patrick H. Roseboom, et al.

Art Unit

Examiner Name

Attorney Docket Number

960296.98687

### OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Arborelius L, Owens MJ, Plotsky PM, Nemeroff CB (1999) The role of corticotropin-releasing factor in depression and anxiety disorders. J Endocrinol 160:1-12.	
		Baker DG, West SA, Nicholson WE, Ekhtor NN, Kasckow JW, Hill KK, Bruce AB, Orth DN, Geraciotti TD, Jr. (1999) Serial CSF corticotropin-releasing hormone levels and adrenocortical activity in combat veterans with posttraumatic stress disorder. Am J Psychiatry 156:585-588.	
		Bakshi VP, Smith-Roe S, Newman SM, Grigoriadis DE, Kalin NH (2002) Reduction of stress-induced behavior by antagonism of corticotropin-releasing hormone 2 (CRF2) receptors in lateral septum or CRF1 receptors in amygdala. J Neurosci 22:2926-2935.	
		Beglinger C, Degen L (2002) Role of thyrotrophin releasing hormone and corticotrophin releasing factor in stress related alterations of gastrointestinal motor function. Gut 51 Suppl 1:145-149.	
		Behan DP, De Souza EB, Lowry PJ, Potter E, Sawchenko P, Vale WW (1995) Corticotropin releasing factor (CRF) BP: a novel regulator of CRF and related peptides. Front Neuroendocrinol 16:362-382.	
		Behan DP, Khongsaly O, Owens JJ, Chung HD, Nemeroff CB, DeSouza EG (1997) Corticotropin-Releasing Factor (CRF), CRF-BP (CRF-BP), and CRF/CRF-BP Complex in Alzheimer's Disease and Control Postmortem Human Brain. Journal of Neurochemistry 68:2053-2060.	
		Bremner JD, Licinio J, Darnell A, Krystal JH, Owens MJ, Southwick SM, Nemeroff CB, Charney DS (1997) Elevated CSF corticotropin-releasing factor concentrations in posttraumatic stress disorder. Am J Psychiatry 154:624-629.	
		Chappell P, Leckman J, Goodman W, Bissette G, Pauls D, Anderson G, Riddle M, Scahill L, McDougale C, Cohen D (1996) Elevated cerebrospinal fluid corticotropin-releasing factor in Tourette's syndrome: comparison to obsessive compulsive disorder and normal controls. Biol Psychiatry 39:776-783.	
		Chen R, Lewis KA, Perrin MH, Vale WW (1993) Expression cloning of a human corticotropin-releasing-factor receptor. Proc Natl Acad Sci U S A 90:8967-8971.	
		Cortright D, Goosens K, Lesh J, Seasholtz A (1997) Isolation and characterization of the rat corticotropin-releasing hormone (CRF) BP gene: Transcriptional regulation by cyclic adenosine monophosphate and CRF. Endocrinology 138:2098-2108.	

Examiner  
Signature

Date  
Considered

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		Application Number	10/676,526
		Filing Date	10/01/2003
		First Named Inventor	Patrick H. Roseboom, et al.
		Group Art Unit	--
		Examiner Name	--
		Attorney Docket Number	960296.98687
Sheet	2	of	4

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Coste SC, Quintos RF, Stenzel-Poore MP (2002) Corticotropin-releasing hormone-related peptides and receptors. Emergent regulators of cardiovascular adaptations to stress. Trends Cardiovasc Med 12:176-182.	
		Fossey MD, Lydiard RB, Ballenger JC, Laraia MT, Bissette G, Nemeroff CB (1996) Cerebrospinal fluid corticotropin-releasing factor concentrations in patients with anxiety disorders and normal comparison subjects. Biol Psychiatry 39:703-707.	
		Gasparotto OC, Ignacio ZM, Lin K, Goncalves S (2002) The effect of different psychological profiles and timings of stress exposure on humoral immune response. Physiol Behav 76:321-326.	
		Guillemin R, Rosenberg B (1955) Humoral hypothalamic control of anterior pituitary: a study with combined tissue cultures. Endocrinology 57:599-607.	
		Kostich WA, Chen A, Sperle K, Largent BL (1998) Molecular identification and analysis of a novel human corticotropin- releasing factor (CRF) receptor: the CRF2gamma receptor [In Process Citation]. Mol Endocrinol 12:1077-1085.	
		Lewis K, Li C, Perrin MH, Blount A, Kunitake K, Donaldson C, Vaughan J, Reyes TM, Gulyas J, Fischer W, Bilezikjian L, Rivier J, Sawchenko PE, Vale WW (2001) Identification of urocortin III, an additional member of the corticotropin-releasing factor (CRF) family with high affinity for the CRF2 receptor. Proc Natl Acad Sci U S A 98:7570-7575.	
		Linton EA, Behan DP, Saphier PW, Lowry PJ (1990) Corticotropin-Releasing Hormone (CRF)-BP: Reduction in the Adrenocorticotropin-Releasing Activity of Placental but not Hypothalamic CRF. Journal of Endocrinology and Metabolism 70:1574-1580.	
		Lovenberg TW, Liaw CW, Grigoriadis DE, Clevenger W, Chalmers DT, De Souza EB, Oltersdorf T (1995) Cloning and characterization of a functionally distinct corticotropin- releasing factor receptor subtype from rat brain [published erratum appears in Proc Natl Acad Sci U S A 1995 Jun 6;92(12):5759]. Proc Natl Acad Sci U S A 92:836-840.	
		McGaugh JL, Roozendaal B (2002) Role of adrenal stress hormones in forming lasting memories in the brain. Curr Opin Neurobiol 12:205-210.	
		Mitchell AJ (1998) The role of corticotropin releasing factor in depressive illness: a critical review. Neurosci Biobehav Rev 22:635-651.	
		Nemeroff CB (1989) Clinical Significance of Psychoneuroendocrinology in Psychiatry: Focus on the Thyroid and Adrenal. J Clin Psychiatry 50:13-20.	

Examiner Signature	Date Considered
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/676,526
				Filing Date	10/01/2003
				First Named Inventor	Patrick H. Roseboom, et al.
				Group Art Unit	--
				Examiner Name	--
Sheet	3	of	4	Attorney Docket Number	960296.98687

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Perrin M, Donaldson C, Chen R, Blount A, Berggren T, Bilezikjian L, Sawchenko P, Vale W (1995) Identification of a second corticotropin-releasing factor receptor gene and characterization of a cDNA expressed in heart. Proc Natl Acad Sci USA 92:2969-2973.	
		Potter E, Behan DP, Fischer WH, Linton EA, Lowry PJ, Vale WW (1991) Cloning and characterization of the cDNAs for human and rat corticotropin releasing factor-BPs. Nature 349:423-425.	
		Reul JM, Holsboer F (2002) Corticotropin-releasing factor receptors 1 and 2 in anxiety and depression. Curr Opin Pharmacol 2:23-33.	
		Reyes TM, Lewis K, Perrin MH, Kunitake KS, Vaughan J, Arias CA, Hogenesch JB, Gulyas J, Rivier J, Vale WW, Sawchenko PE (2001) Urocortin II: A member of the corticotropin-releasing factor (CRF) neuropeptide family that is selectively bound by type 2 CRF receptors. Proc Natl Acad Sci U S A 98:2843-2848.	
		Tache Y, Martinez V, Million M, Wang L (2001) Stress and the gastrointestinal tract III. Stress-related alterations of gut motor function: role of brain corticotropin-releasing factor receptors. Am J Physiol Gastrointest Liver Physiol 280:G173-177.	
		Takahashi LK (2001) Role of CRF(1) and CRF(2) receptors in fear and anxiety. Neurosci Biobehav Rev 25:627-636.	
		Takahashi LK, Ho SP, Livanov V, Graciani N, Arneric SP (2001) Antagonism of CRF(2) receptors produces anxiolytic behavior in animal models of anxiety. Brain Res 902:135-142.	
		Vanitallie TB (2002) Stress: A risk factor for serious illness. Metabolism 51:40-45.	
		Vaughan J, Donaldson C, Bittencourt J, Perrin MH, Lewis K, Sutton S, Chan R, Turnbull AV, Lovejoy D, Rivier C, et al. (1995) Urocortin, a mammalian neuropeptide related to fish urotensin I and to corticotropin-releasing factor. Nature 378:287-292.	
		Veith RC, Lewis N, Langohr JI, Murburg MM, Ashleigh EA, Castillo S, Peskind ER, Pascualy M, Bissette G, Nemeroff CB, Raskind MA (1993) Effect of desipramine on cerebrospinal fluid concentrations of corticotropin-releasing factor in human subjects. Psychiatry Res 46:1-8.	
		Zobel AW, Nickel T, Kunzel HE, Ackl N, Sonntag A, Ising M, Holsboer F (2000) Effects of the high-affinity corticotropin-releasing hormone receptor 1 antagonist R121919 in major depression: the first 20 patients treated. J Psychiatr Res 34:171-181.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Application Number</b>	10/676,526
				<b>Filing Date</b>	10/01/2003
				<b>First Named Inventor</b>	Patrick H. Roseboom, et al.
				<b>Group Art Unit</b>	--
				<b>Examiner Name</b>	--
				<b>Attorney Docket Number</b>	960296.98687
<b>Sheet</b>	4	<b>of</b>	4		

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Behan, Dominic C., et al. (1995) Displacement of corticotropin releasing factor from its binding protein as a possible treatment for Alzheimer's disease. Nature 378:284-287.	
		Behan, Dominic C., et al. (1992) Cloning and Structure of the Human Corticotrophin Releasing Factor-Binding Protein Gene (CRHBP). Genomics 16:63-68.	

<b>Examiner Signature</b>		<b>Date Considered</b>	
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# FEE TRANSMITTAL

## for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$) 180.00
**Complete if Known**

Application Number	10/676,526
Filing Date	10/01/2003
First Named Inventor	Patrick H. Roseboom, et al.
Examiner Name	--
Art Unit	--
Attorney Docket No.	960296.98687

**METHOD OF PAYMENT** (check all that apply)
☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

 Deposit  
Account  
Number  
Deposit  
Account  
Name

17-0055

Quarles &amp; Brady LLP

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.
**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
<b>SUBTOTAL (1)</b>					<b>(\$)</b> 0.00

**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

Total Claims		Extra Claims		Fee from below		Fee Paid
Independent	Claims					
		-20*	=		X	0.00
		-3**	=		X	0.00
Multiple Dependent						

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

**SUBTOTAL (2)** (\$)

\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION** (continued)**3. ADDITIONAL FEES**

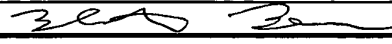
Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180.00
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3)** (\$)**SUBMITTED BY**

(Complete if applicable)

Name (Print/Type)	Zhibin Ren	Registration No. (Attorney/Agent)	47,897	Telephone	414-277-5633
Signature		Date	2/27/2004		

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